All communications respecting this application should give the serial number, date of filing and name of the applicant.



U. S. DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Application Number						
Application Number 09/756,411	Filing Date	First Named Applicant	Attorney Docket Number			
09//30,411	01/08/01	Lori	NIH061.1CP1C2			
			Examiner			
		L. E. Crane				
			Art Unit Paper No.			
		,	1623 11			
••	INTERVI	EW SUMMARY	DATE MAILED: <u>n/a</u>			
All participants (applicant, app (1) Ms. Nancy W. Vensko (2) Examiner L. E. Crane	licant's representative PT	O personnel) (3) (4)				
Date of Interview: <u>02/11/03.</u>						
Type: X Telephonic -	Personal (copy given to)	- applicant - a	applicant's representative			
Exhibit shown or demonstration co	nducted: - Yes X	No If yes, brief descrip	tion: See attachment.			
Agreement _ was reached to	with respect to some of all of t	he claims in question.	X was not reached			
Claim(s) discussed: See page 2	<u>2.</u>					
Identification of prior art discuss	sed: <u>See page 2.</u>					
Description of the general natur	e of what was agreed to if	an agreement was reache	ed, or any other comment: See p. 2.			
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Examiner Note: You must: PTOL-413 (amended 03/13	sign this form unless in	t is an attachment to a	another form.			
09/756,411 - P. N. <u>11</u>		File [] Applicant	Continued on next pag (s) ->->			

2

Art Unit 1623

INTERVIEW SUMMARY(cont.)

Claims discussed: All remaining of record, but no claims in particular.

Identification of prior art discussed: NONE.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: Applicant requested examiner's view concerning the possibility of a declaration under 37 CFR §1.132 signed by Dr. Vila and indicating predictability in the area of anti-HIV effectiveness by mixtures of antiviral nucleoside analogues and hydroxyurea. Applicant was advised that examiner continued to consider the fundamental problem of the '411 application to be lack of data in support of extrapolation from the findings of Malley and (Dr.) Vila (see also their issued patents) to the compositions of the instant claims. Applicant suggested and examiner concurred that the guidance provided by Ex parte Balzarini (21 USPO 2d 1892 (BPAI, 1991) applies to the instant case, but that the instant fact patterns are not precisely identical. Examiner deferred specific comment on the contents of the proposed declaration until examiner has had an opportunity to review the declaration and any other submissions by applicant.

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DATE MAILED: n/a INTERVIEW SUMMARY All participants (applicant, applicant's representative, PTO personnel) (1) Ms. Nancy W. Vensko, Esq. (3) Ms. Marina L. Gordey, Ph.D. (2) Examiner L. E. Crane, Ph.D., Esq. (4) Mr. Eric Ives, Ph.D. Date of Interview: 11/15/02. Type: Telephonic X Personal (copy given to) applicant X applicant's representative Exhibit shown or demonstration conducted: Yes X No If yes, brief description: See attachment.	Application Number	Filing Date	First Named Applicant	Attorney Docket Number						
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09/756.411 - P. N. 10 COPY FOR 1/1 File [] Applicant Continued n next page(s) ->->	•		th File 11 Applicant	On white so it						

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Art Unit 1623

INTERVIEW SUMMARY(cont.)

Claims discussed: All remaining of record, claims 21-30 in particular.

Identification of prior art discussed: The prior art already of record.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: Applicant was advised that examiner considered the enablement issue to be governed by the guidance provided by Gentry Gallery, Inc. v. Berkline Corp (134 F.3d 1473, 45 USPO2d 1498 (Fed. Cir. 1998)) and, more specifically Regents of Univ. of Cal. v. Eli Lilly & Co. (119 F.3d 1559, 43 USPO2d 1398 (Fed. Cir. 1997)) and Ex parte Balzarini et al. (21 USPO2d 1892 (BPAI 1991)). Examiner also indicated that uncertainty concerning what test protocols correlate with human test results remained in the art area, citing the clear statement of Malley et al. in the '161 patent abstract that the combination of hydroxyurea and AZT was ineffective against HIV in cell culture, a direct contradiction of the allegations of the instant application. Examiner and applicant did not reach any conclusions concerning what was allowable.